

III. Remarks

Claims 1-39 were previously pending, of which claims 11, 12, and 31-36 were previously withdrawn for being directed to a non-elected species. Reconsideration of claims 1-10, 13-30, and 37-39 is requested in light of the following remarks.

Premature Final Rejection

As a preliminary matter, Applicant requests that the finality of the Office Action be withdrawn. As set forth clearly in MPEP §706.07(a):

“Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant’s amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c)....”

In the present case, the new ground of rejection for at least claims 1, 2, 5, and 7-10 under 35 U.S.C. §103 is neither necessitated by an amendment made by the Applicant nor information submitted in a IDS filed under 37 CFR 1.97(c). In particular, claims 1, 2, 5, and 7-10 remain pending as previously considered in the Office Action mailed May 1, 2007 where they were rejected under 35 U.S.C. §102. Further, the Marnay application cited as supporting the new ground of rejection was not submitted in a IDS filed during the period set forth in 37 CFR 1.97(c).

As noted above, claims 1, 2, 5, and 7-10 have not been amended, yet stand rejected in the current Office Action based on new grounds. In that regard, MPEP §706.07(a) notes:

“Furthermore, a second or any subsequent action on the merits in any application ... will not be made final if it includes a rejection, on newly cited art, ... in spite of the fact that other claims may have been amended to require newly cited art.”

Thus, Applicants assert that the Office Action has been improperly made final. For at least these reasons Applicants request that the finality of the Office Action be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 1-10, 13-30, and 37-39 stand rejected under 35 U.S.C. §103(a) as being unpatentable over WO 01/01893 to Marnay et al. (“the Marnay application”). Applicants respectfully traverse the rejection of these claims on the grounds that a *prima facie* case of obviousness has not been established.

In *KSR Int'l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007), the Court stated that “**a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.** Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a **reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.** This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *Id.* at 1741 (emphasis added).

As the PTO recognizes in MPEP § 2142:

... The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness...

It is submitted that the examiner has not factually supported a *prima facie* case of obviousness with respect to claims 1-10, 13-30, and 37-39 in the present case.

With respect to independent claim 1, the Marnay application at least fails to disclose or suggest, “a projection extending from a first articular surface, the projection being offset relative to the first articular surface ... a recess formed in a second articular surface, the recess being offset relative to the second articular surface thereby accommodating a spondylosed relationship between a first vertebra and a second vertebra adjacent to the first vertebra, wherein the projection and the recess engage one another to provide for articulating motion between the first and second components.” In that regard, as shown in Figures 1 and 7 reproduced below, the parts 2 and 3 of the Marnay application are configured to be substantially aligned, as indicated

by the dotted lines. To that end, the spherically upwardly-curved topside 25 of the pivot insert 4 is centrally positioned and configured to mate with the centrally positioned concave spherical indentation 12 of the upper part 2.

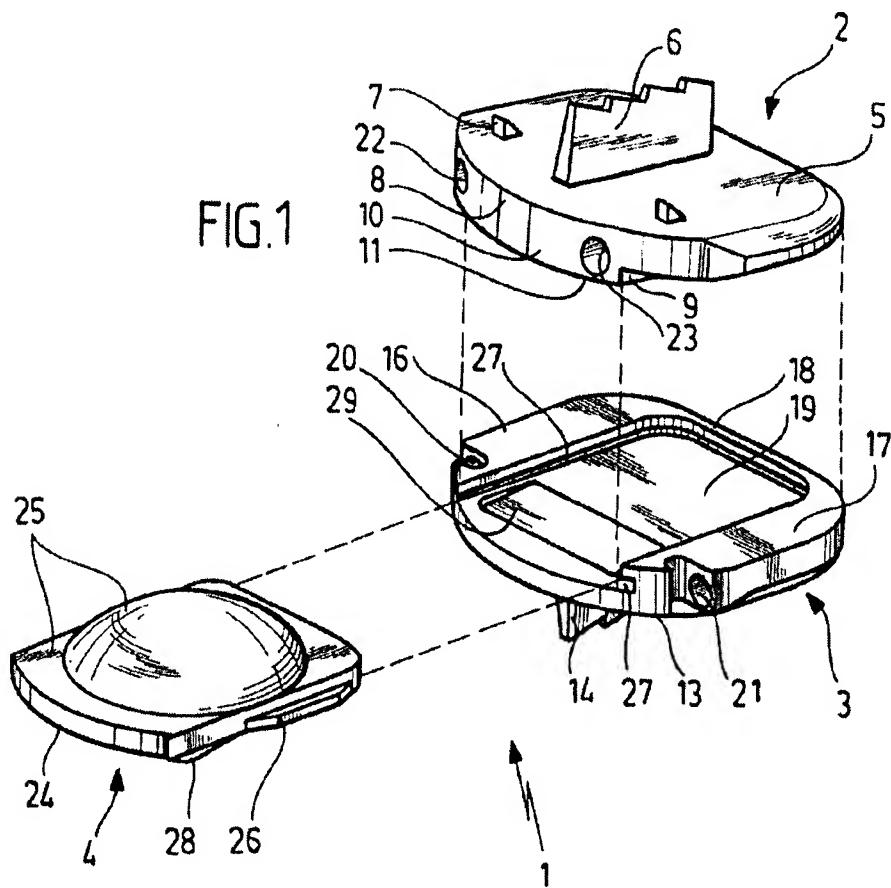
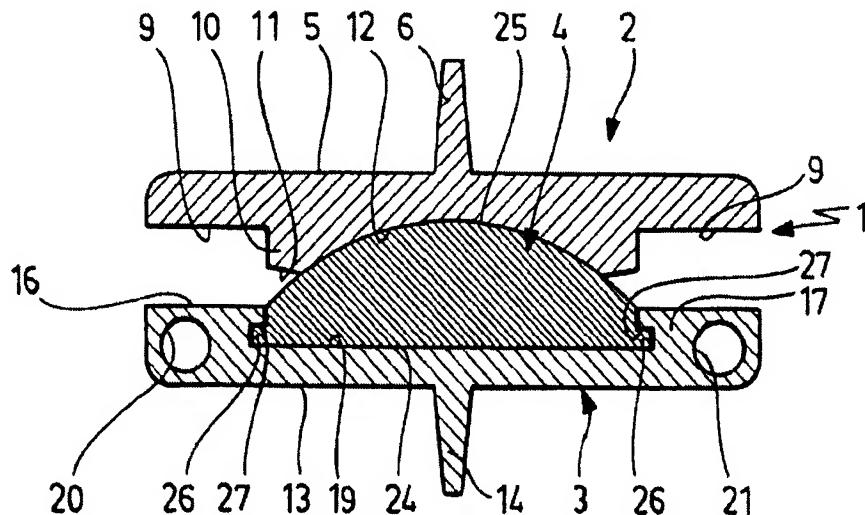


FIG.7



Accordingly, the implant 1 of the Marnay application clearly does not disclose or suggest having a projection offset relative to the first articular surface articulatingly engaged with a recess offset relative to the second articular surface surface, thereby accommodating a spondylosed relationship between a first vertebra and a second vertebra, as required by claim 1.

Further, there is no reason—other than hindsight based on the present application—for modifying the positions of the spherical indentation 12 and the spherically upward-curved top side 25 of the Marnay application to be in offset positions to accommodate a spondylosed relationship between vertebrae. In that regard, the Marnay application does not even mention spondylosed vertebrae or a device for accommodating spondylosed vertebrae. However, the Office Action asserts that “it would have been obvious ... to have located the articulation features at any location or distance or range of distances from an edge or edges of the device, since it has been held that mere relocation of parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.” Applicants disagree that such a modification would be a mere relocation of parts similar to that of *In re Japikse*, where “[c]laims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were held unpatentable because shifting the position of the starting switch would not have modified the operation of the device.” MPEP §2144.04. Moving the articulation features to offset positions to accommodate a

spondylosed relationship would not simply require relocating parts, but would require the creation of entirely new parts having the recited features. Accordingly, Applicants submit that it would not have been obvious to modify the components of the Marnay application as suggested to accommodate a spondylosed relationship.

For at least these reasons, a *prima facie* case of obviousness has not been established with respect to independent claim 1. Claims 2-10 depend from and further limit independent claim 1. Therefore, Applicants respectfully request that the §103 rejection of claims 1-10 over the Marnay application be withdrawn.

With respect to independent claim 13, the Marnay application at least fails to teach, “wherein one of the first and second components comprises a projection and the other of the first and second components comprises a recess, the projection and recess being adapted to engage one another, and wherein one of the projection and the recess is offset relative to the other of the projection and the recess to accommodate a spondylosed relationship between the first and second vertebrae.” As discussed above with respect to claim 1, the parts 2, 3 and insert 4 of the implant 1 of the Marnay application are configured to be substantially aligned. The Marnay application simply does not disclose a prosthetic device having components with offset projection and recess to accommodate a spondylosed relationship between vertebrae as required by claim 13 and no reason for modifying the prosthetic device to include such limitations has been established.

For at least these reasons, a *prima facie* case of obviousness has not been established with respect to independent claim 13. Claims 14-30 depend from and further limit claim 13. Therefore, Applicants respectfully request that the §103 rejection of claims 13-30 over the Marnay application be withdrawn.

With respect to independent claim 37, the Marnay application at least fails to teach, “longitudinally inserting the first articular component into a first vertebra and longitudinally inserting the second articular component into a second vertebra, the second vertebra being adjacent to and in a spondylosed relationship with the first vertebra.” Again, the Marnay application simply does not disclose a inserting articular components of a prosthetic device

between adjacent vertebrae that are in a spondylosed relationship. As noted above, the Marnay application does not even mention spondylosed vertebrae or providing a device for accommodating spondylosed vertebrae. This is consistent with the fact that the parts 2, 3 and insert 4 of the implant 1 of the Marnay application are configured to be substantially aligned. The Marnay application simply does not disclose such limitations as required by claim 37 and no reason for modifying the disclosure of the Marnay application to include such limitations has been established.

For at least these reasons, a *prima facie* case of obviousness has not been established with respect to independent claim 37. Claims 38 and 39 depend from and further limit claim 37. Therefore, Applicants respectfully request that the §103 rejection of claims 37-39 over the Marnay application be withdrawn.

IV. Conclusion

Applicants believe that all matters set forth in the Office Action have been addressed and that claims 1-10, 13-30, and 37-39 are in condition for allowance. An early formal notice of allowance is requested.

Should the Examiner deem that an interview with Applicants' undersigned attorney would expedite consideration of the present application, the Examiner is invited to call the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

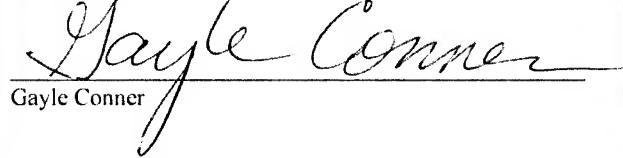


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I hereby certify that this correspondence is being filed with the United States Patent and Trademark Office via EFS-Web on January 2, 2008.



Gayle Conner